

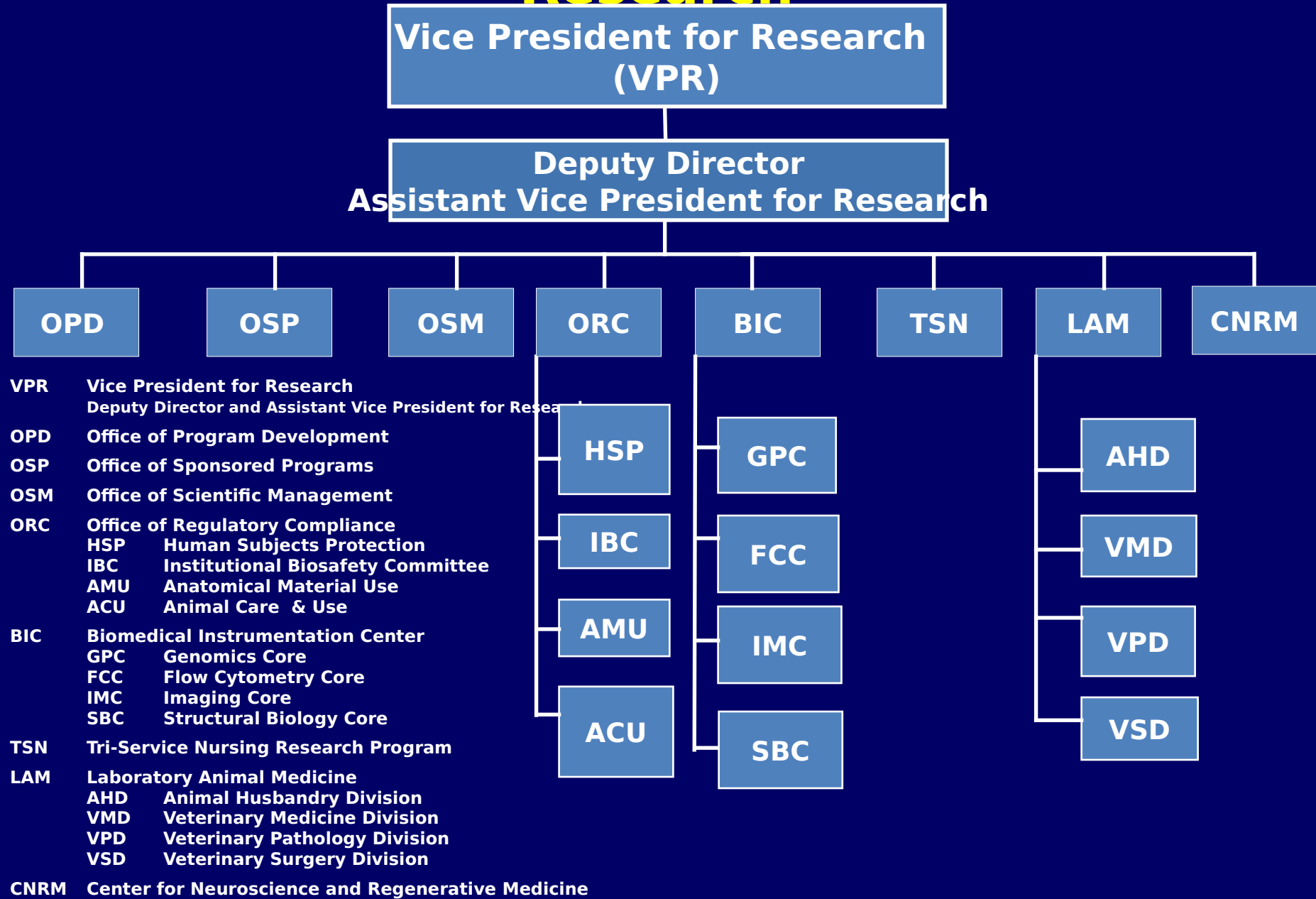
# **Office of Research**

## **Uniformed Services University of the Health Sciences**

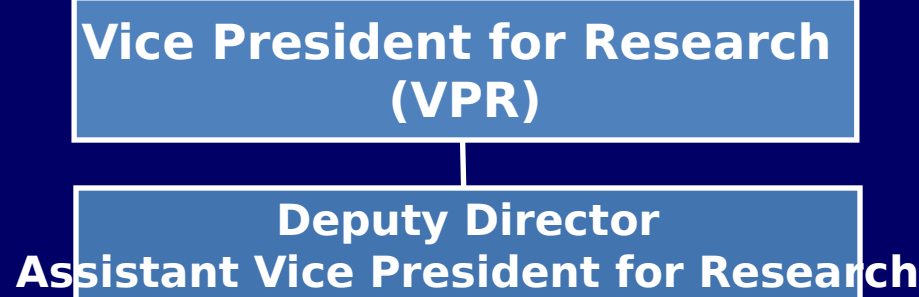
**Steven G. Kaminsky, Ph.D.  
Vice President for Research**

**13 October 2011**

# Organizational Chart for Vice President for Research



# Organizational Chart for Vice President for Research



VPR	Vice President for Research Deputy Director and Assistant Vice President for Research
OPD	Office of Program Development
OSP	Office of Sponsored Programs
OSM	Office of Scientific Management
ORC	Office of Regulatory Compliance
HSP	Human Subjects Protection
IBC	Institutional Biosafety Committee
AMU	Anatomical Material Use
ACU	Animal Care & Use
BIC	Biomedical Instrumentation Center
GPC	Genomics Core
FCC	Flow Cytometry Core
IMC	Imaging Core
SBC	Structural Biology Core
TSN	Tri-Service Nursing Research Program
LAM	Laboratory Animal Medicine
AHD	Animal Husbandry Division
VMD	Veterinary Medicine Division
VPD	Veterinary Pathology Division
VSD	Veterinary Surgery Division
CNRM	Center for Neuroscience and Regenerative Medicine

# **Office of Program Development (OPD)**

Susan B. Rasmussen, Ph.D.

Director

[srasmussen@usuhs.mil](mailto:srasmussen@usuhs.mil)

301-295-3303

# **Office of Program Development: Roles of the Intramural Research Program**

- Enables USU faculty to begin research directed at maintaining a fit and healthy force
- Enables USU to recruit and retain high quality clinician-investigators and biomedical scientists
- Enhances USU faculty's ability to compete for extramural research funds
- Supports training of the next generation of government medical research scientists and physicians with sound understanding of the scientific basis of good medicine
- Supports continued academic accreditation for the University's programs in higher education

# Office of Program Development: Intramural Research Program

Award Type	Funding Ceiling	Project Period
Exploratory	\$75,000 per year	Up to 24 months
Standards	\$20,000 per year	Up to 36 months
Pilots	\$10,000 per year	Up to 24 months
Instructional	\$10,000 per year	Up to 24 months
Clinical Fellows	\$3,000 per year	Up to 24 months
Graduate Students	\$2,500 per year	Up to 24 months
Medical Students	\$1,000 per year	Up to 12 months
Startup Equipment	Negotiated at hiring	24 months
Startup Personnel	Negotiated at hiring	36 months
Startup Supplies	Negotiated at hiring	Up to 60 months

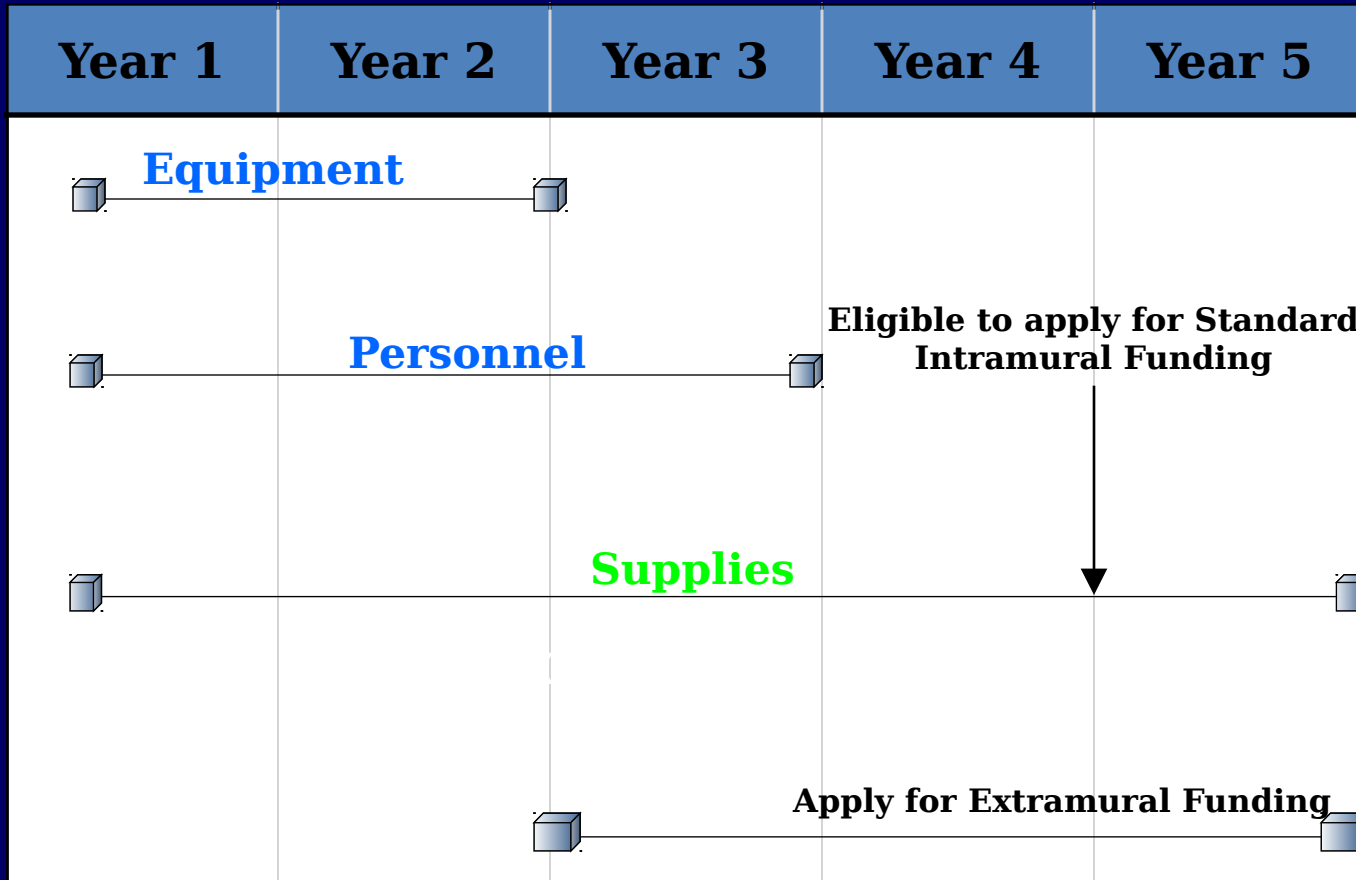
# USU Intramural Program “Evolution of Funding”



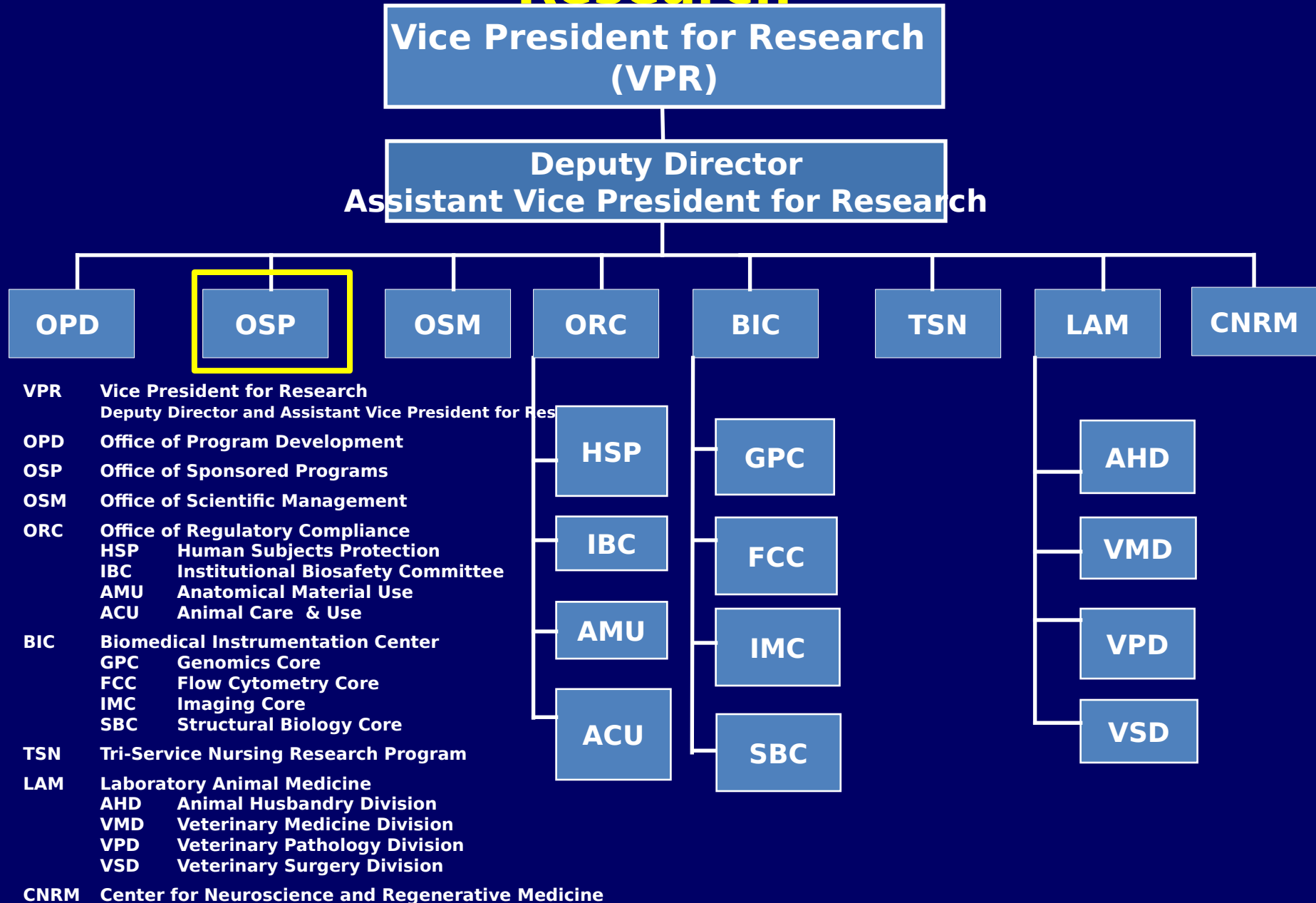
# Start Up Funding

Mr. Steve Rice  
VP of Finance

Dr. Steve Kaminsky  
VP of Research



# Organizational Chart for Vice President for Research



# **Office of Sponsored Programs (OSP)**

Toya V. Randolph, Ph.D.,  
MSPH

Director

[trandolph@usuhs.mil](mailto:trandolph@usuhs.mil)

301-295-3303

# USU OSP - Overview & Mission

- Oversees administrative activities related to the **pre- and post-award** management of **extramural** research projects for USU faculty & AFRRI scientists
- Strives to provide friendly, efficient, courteous, & knowledgeable service
- Team of Grants Management Specialists to assist with extramural application submissions
- Each department has an assigned Specialist
- Works with the Henry M. Jackson Foundation for a smooth and efficient transition of USU applications & awards
- Open door policy

# Henry M. Jackson Foundation

- Created in 1983 as a non-profit corporation
- Chartered by Congress to “promote the welfare of the Uniformed Services University...”
  - Supports many USU research projects
  - Over 400 employees at USU, more than 80 with Visas
    - Including Sponsored Project Administrators (SPA) for every academic department at USU
- Technology Transfer
- Located 6 miles north of USU on Rockledge Drive

# HJF Contacts

Betsy Folk

VP Office of Sponsored Projects

[osp@hjf.org](mailto:osp@hjf.org)

240-694-2020

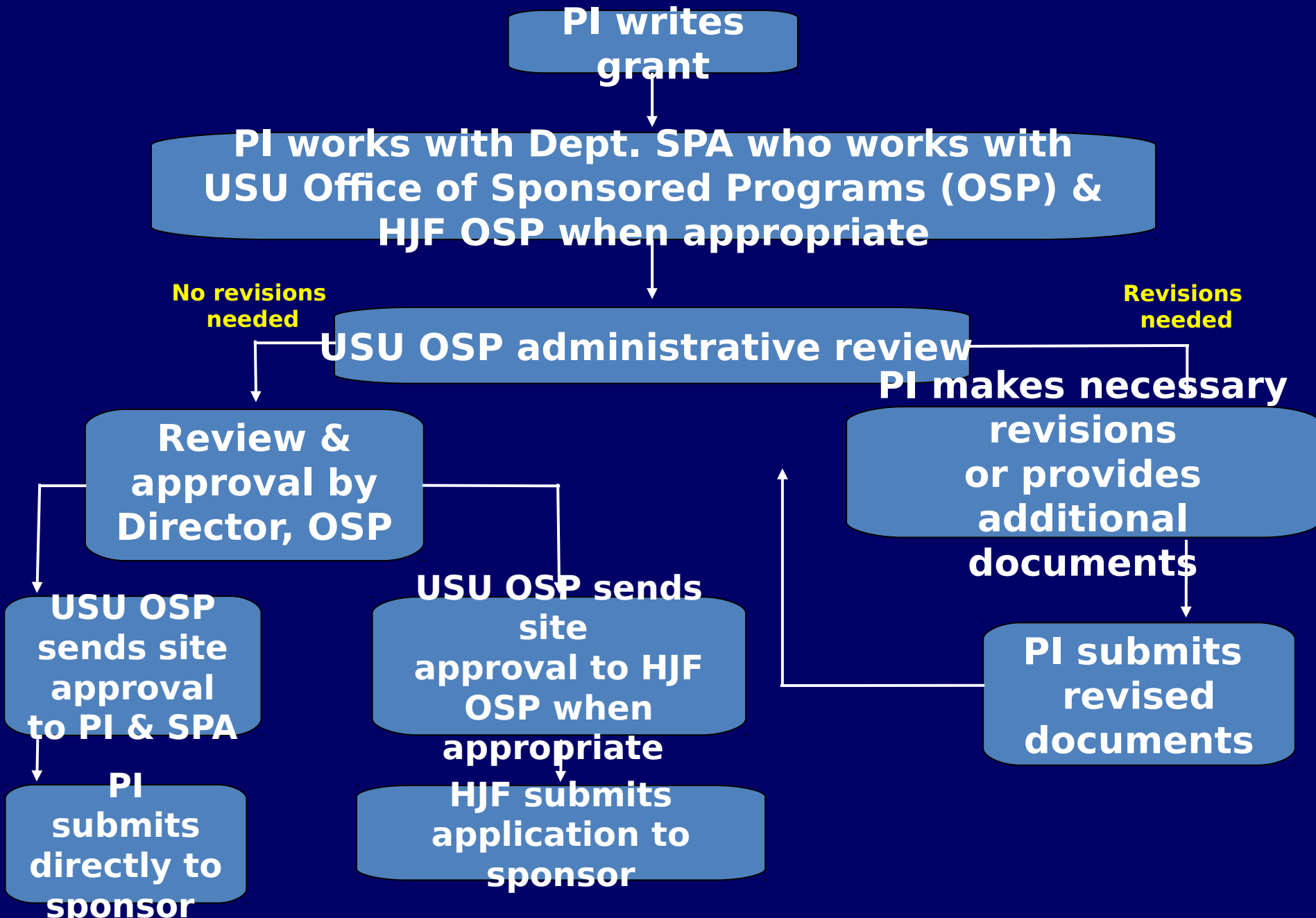
Alyssa Shepard, Ph.D.

Director, USU Services

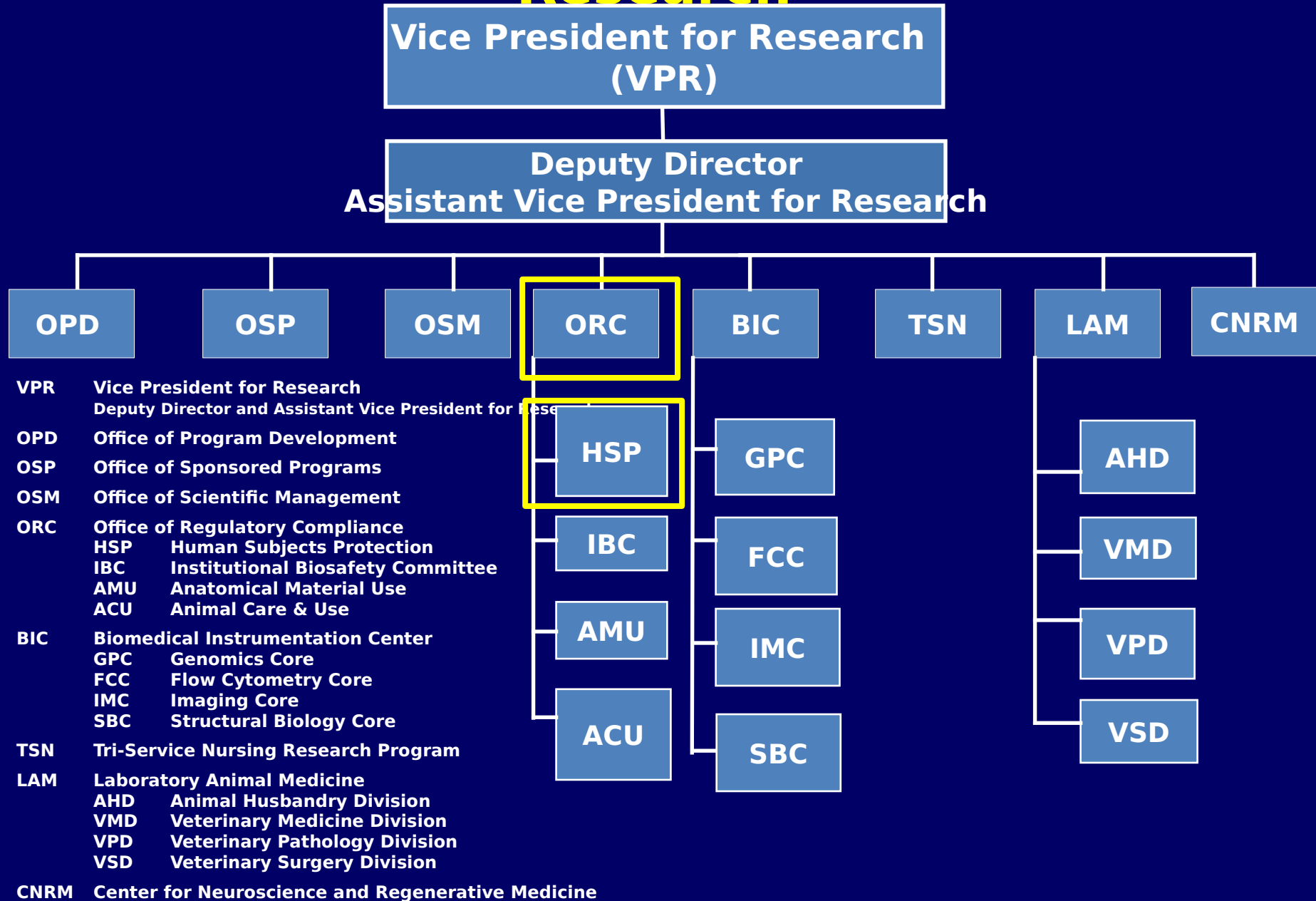
[ashepard@usuhs.mil](mailto:ashepard@usuhs.mil) or [USUServices@hjf.org](mailto:USUServices@hjf.org)

240-694-2087

# Extramural Funding Submission Process



# Organizational Chart for Vice President for Research



# **Institutional Review Board (IRB)**

Ms. Maggie Pickerel, CIP  
Director, Human Research Protections Program  
mpickerel@usuhs.mil  
IRB Office (A2051)  
301-295-9534

# IRB

## Chair: IRB #1

Edmund (Randy) Howe,  
M.D., J.D.

[ehowe@usuhs.mil](mailto:ehowe@usuhs.mil)

301-295-3097

## IRB #1 Administrator

Micah Stretch, J.D.  
[mstretch@usuhs.mil](mailto:mstretch@usuhs.mil)

301-295-0819

## Chair: ID IRB

CAPT Trueman Sharp, MC,  
USN

[tsharp@usuhs.mil](mailto:tsharp@usuhs.mil)

301-295-3637

## ID IRB Administrator

Vicki Zajack, MPH, CIP  
[Victoria.zajack.ctr@usuhs.mil](mailto:Victoria.zajack.ctr@usuhs.mil)

301-319-0444

# IRB: Roles and Functions

- Protects the rights and welfare of human research subjects
- Reviews research protocols to assess risks and benefits to subjects in research
- Ensures risks are minimized and reasonable in relationship to anticipated benefits
- Ensures voluntary participation of research, equitable selection, and informed consent
- Ensures compliance with DoD and federal regulations
- Recommends approval, disapproval, modification, tabling of protocols

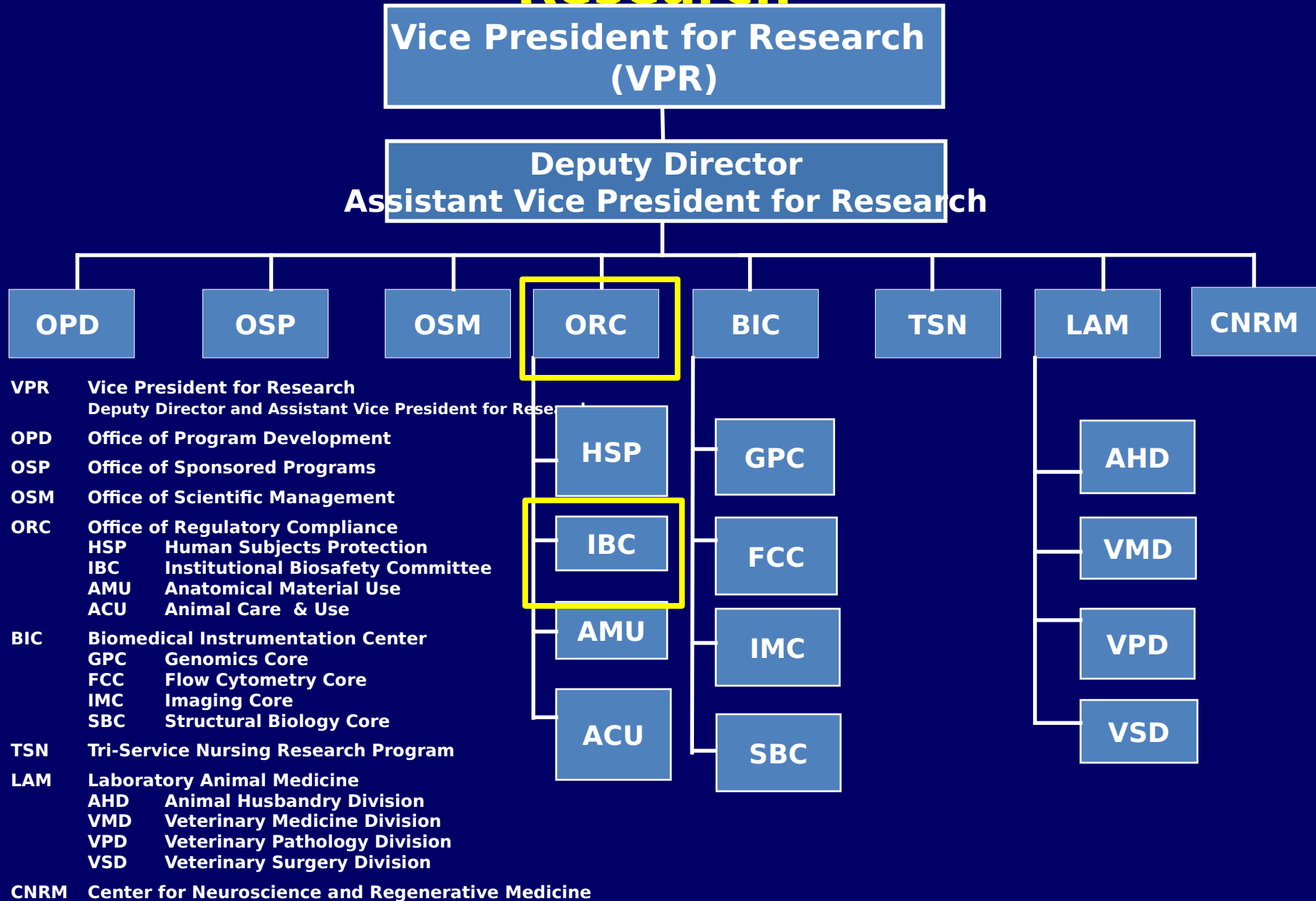
# IRB: PI's Role

- Submit protocol and related paperwork via IRBNet
- Use only the latest forms (located on IRBNet) -- no other forms permissible
- Ensure paperwork is complete -- Only complete paperwork will be reviewed
- List only one PI on the protocol (others are AIs/collaborators)
- Ensure congruence between funded grant and protocol
- Be aware of DoD 'unique' regulations: e.g., no waiver of informed consent for experimental subjects; intent to benefit for subjects unable to provide consent; research monitor for more than minimal risk research; special permission for USU uniformed students as subjects, etc.
- Meet with IRB staff early for guidance, especially for multisite and protocols conducted offsite

# IRB Facts

- USU has 2 IRBs: IRB #1 and the (central) Infectious Disease IRB
- Scheduled meetings: 2<sup>nd</sup> or 3<sup>rd</sup> Thursday
- Types of Protocol Review: Exempt, Expedited, Full Board, Non-human Subjects Research (NHSR)
- Exemption/NHSR determination made **only** by USU Exemption Determination Official (EDO)
- IRB = Privacy Board for HIPAA & Privacy Act issues
- Review/approval times depend upon protocol complexity, scheduling, workload, etc.
- Initial and continuing training required of all key research team members (initial: [www.citiprogram.org](http://www.citiprogram.org))
- Secondary IRB review process required for research performed offsite (e.g., WRNMMC)
- <http://www.usuhs.mil/research/RegPolicies.html>

# Organizational Chart for Vice President for Research



# Institutional Biosafety Committee (IBC)

## Chair

Dr. Gabriela Dveksler  
Dept of Pathology  
gdveksler@usuhs.mil  
301-295-3332

## Peter Bouma

Biosafety Officer  
pbouma@usuhs.mil  
301-295-9443

## Ms. Melanie Hazzard

Regulatory Affairs  
Coordinator  
Melanie.hazzard@usuhs.mil  
1  
301-295-9509

# Institutional Biosafety Committee (IBC)

- Ensures compliance with *NIH Guidelines*
- Reviews protocols with rDNA & pathogens
- Appendix 4 of USUHS 3208 - Assurance Supplement

# EHS Webpage



The screenshot shows the EHS Webpage for the Uniformed Services University of the Health Sciences. The header includes the university's name and a search bar. A navigation menu lists various university departments. The main banner features a circular logo with the text 'PROTECTING THE USUHS FAMILY' and 'ENVIRONMENTAL HEALTH AND OCCUPATIONAL SAFETY', alongside the text 'Environmental Health & Occupational Safety'. The left sidebar contains links for 'EHS Main', 'Divisions' (Industrial Hygiene & Environment, Radiation Safety, Occupational Medicine, Pharmacy, Safety and Occupational Health), 'About EHS', 'Laboratory Safety', and 'Services' (Forms, Fact Sheets, Inspections, USU Instructions, Inventories, Links, Report a Hazard/Safety Concern, Report an Injury, Training, Waste). The main content area is titled 'Protecting the USU Family' and lists 'Points of Contact' (CHEM/BIO WEB ACCESS, RAD WEB ACCESS, LABORATORY DECOMMISSIONING GUIDE), 'Bulletins' (Policy Statements, Guidance, Rights and Responsibilities, COMMITMENT TO HEALTH AND SAFETY, SAFE AND HEALTHFUL WORKPLACE (OSHA Bulletin), DOD SAFETY AND OCCUPATIONAL HEALTH PROTECTION PROGRAM, RADIATION SAFETY PROGRAM ENFORCEMENT POLICY), and 'Our Mission' (To provide for a safe and healthful work environment for all students, faculty and staff in the day to day operations of the Uniformed Services University of the Health Sciences. To protect the University environment, in which we work and live through responsible stewardship and use of the tools, materials and environmental resources entrusted to our care).

UNIFORMED SERVICES UNIVERSITY  
*of the Health Sciences*

SEARCH USU

VISITORS ADMISSIONS STUDENTS ALUMNI FACULTY STAFF MILITARY RESEARCH AFFILIATIONS myUSU

 Environmental Health & Occupational Safety

**EHS Main**

**Divisions**

- Industrial Hygiene & Environment
- Radiation Safety
- Occupational Medicine
- Pharmacy
- Safety and Occupational Health

**About EHS**

- Laboratory Safety

**Services**

- Forms
- Fact Sheets
- Inspections
- USU Instructions
- Inventories
- Links
- Report a Hazard/Safety Concern
- Report an Injury
- Training
- Waste

**Protecting the USU Family**

Points of Contact are listed on each Division page

- CHEM/BIO WEB ACCESS
- RAD WEB ACCESS
- LABORATORY DECOMMISSIONING GUIDE

**Bulletins**

Policy Statements, Guidance, Rights and Responsibilities

[COMMITMENT TO HEALTH AND SAFETY](#)  
[SAFE AND HEALTHFUL WORKPLACE \(OSHA Bulletin\)](#)  
[DOD SAFETY AND OCCUPATIONAL HEALTH PROTECTION PROGRAM](#)  
[RADIATION SAFETY PROGRAM ENFORCEMENT POLICY](#)

**Our Mission:**

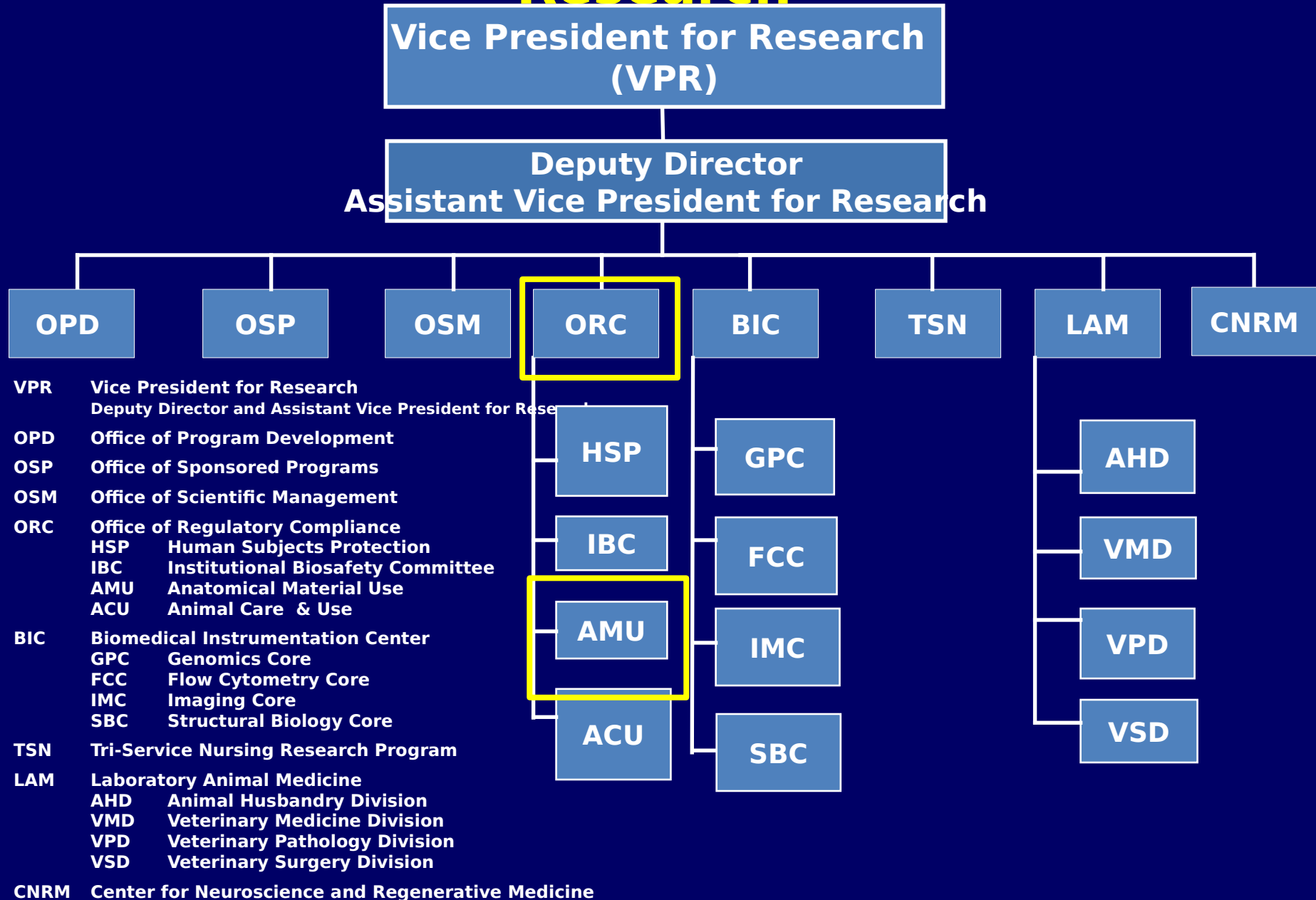
To provide for a safe and healthful work environment for all students, faculty and staff in the day to day operations of the Uniformed Services University of the Health Sciences. To protect the University environment, in which we work and live through responsible stewardship and use of the tools, materials and environmental resources entrusted to our care.

## You can find the following:

- Lab Safety Information & Guidance
- Training Presentations
- Access to EHS Assistant
  - Training records
  - Chem & Bio Inventory
  - Radiation records
- Report an Injury
- Forms & USUHS Instructions
- Waste management
- Contact Information

<http://www.usuhs.mil/ehs/index.html>

# Organizational Chart for Vice President for Research



# Anatomical Material Review Committee (AMRC)

Chair

Alan Seyfer, M.D.

Department of Anatomy, Physiology and Genetics

aseyfer@usuhs.mil

301-295-0441

Ms. Melanie Hazzard

Regulatory Affairs Coordinator

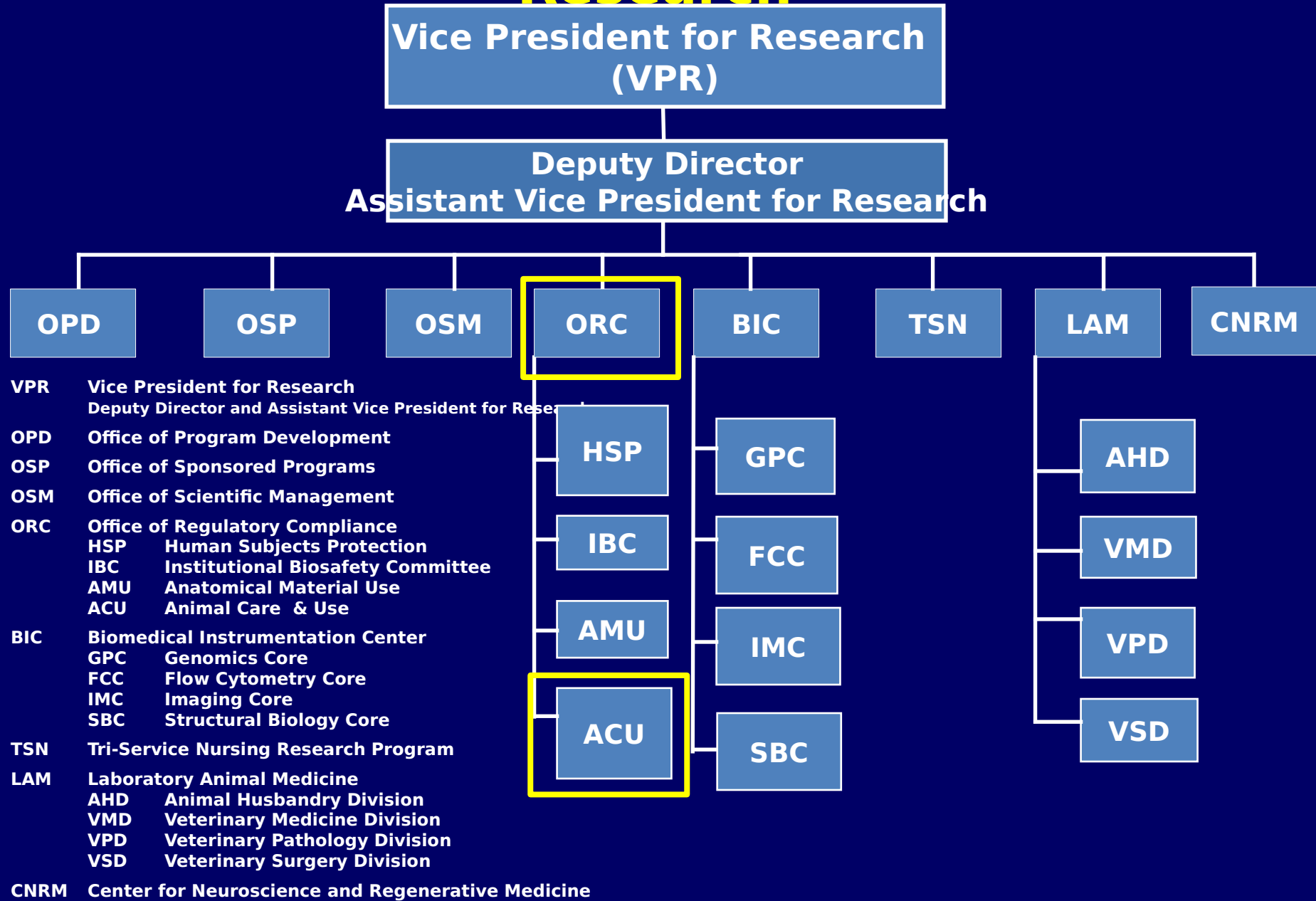
Melanie.hazzard@usuhs.mil

(301) 295-9509

# AMRC

- Reviews the use of human materials in education and research conducted within the Anatomic Teaching Laboratory to ensure that it conforms to the mission of the University and to the appropriate ethical, institutional, and regulatory standards
- Meetings held at least quarterly (6/year typical)
- *<http://www.usuhs.mil/research/RegPolicies.html>*

# Organizational Chart for Vice President for Research



# Institutional Animal Use and Care Committee (IACUC)

## IACUC Chair

Brian Cox, Ph.D.

Dept. of  
Pharmacology

[bcox@usuhs.mil](mailto:bcox@usuhs.mil)

301-295-3223

## IACUC Administrator

Ms. Megan Ralls

[iacuc@usuhs.mil](mailto:iacuc@usuhs.mil)

301-295-3579

## IACUC Coordinator

Ms. Susan Hunt

[iacuc@usuhs.mil](mailto:iacuc@usuhs.mil)

301-295-9504

# IACUC's Roles and Functions

- Reviews animal use protocols
- Reviews significant changes to protocols
- Monitors animal care and use program
- Ensures PI and University compliance with animal welfare regulations
- Inspects CAF and labs with animals 2/year
- Reviews concerns about animal care/use
- Reports out noncompliance and suspensions to OLAW and ASD(HA)

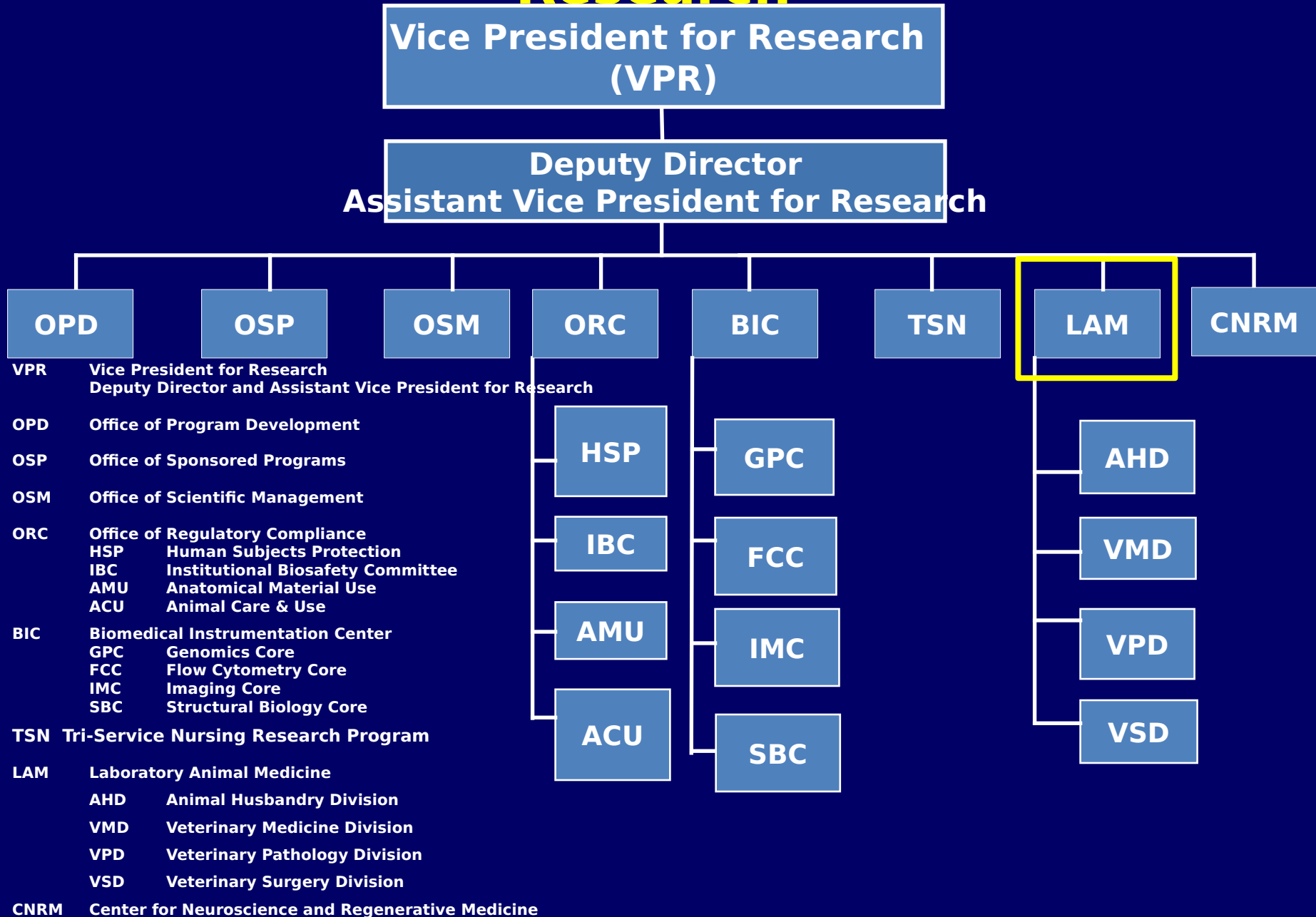
# IACUC: PI's Role

- Describe use of animals in grant application(s)
- Obtain IACUC approval prior to using animals or implementing significant protocol changes
- Ensure research is conducted in accordance with the protocol
- Comply with institutional policies and procedures
- Submit amendments for any major changes, including any change in scope of work
- Address significant changes in the progress report

# IACUC Facts

- Meetings held monthly (3<sup>rd</sup> Wednesday)
- Much routine business conducted electronically via email
- New protocols have mandatory vet review before IACUC review
- Protocol approval is for 3 years
- Annual review must be performed to ensure protocol compliance
- *<http://www.usuhs.mil/research/RegPolicies.html>*

# Organizational Chart for Vice President for Research



# **Laboratory of Animal Medicine (LAM)**

LTC Timothy Settle, DVM, DACVPM, DACLAM  
Director

[timothy.settle@usuhs.mil](mailto:timothy.settle@usuhs.mil)

301-295-3753

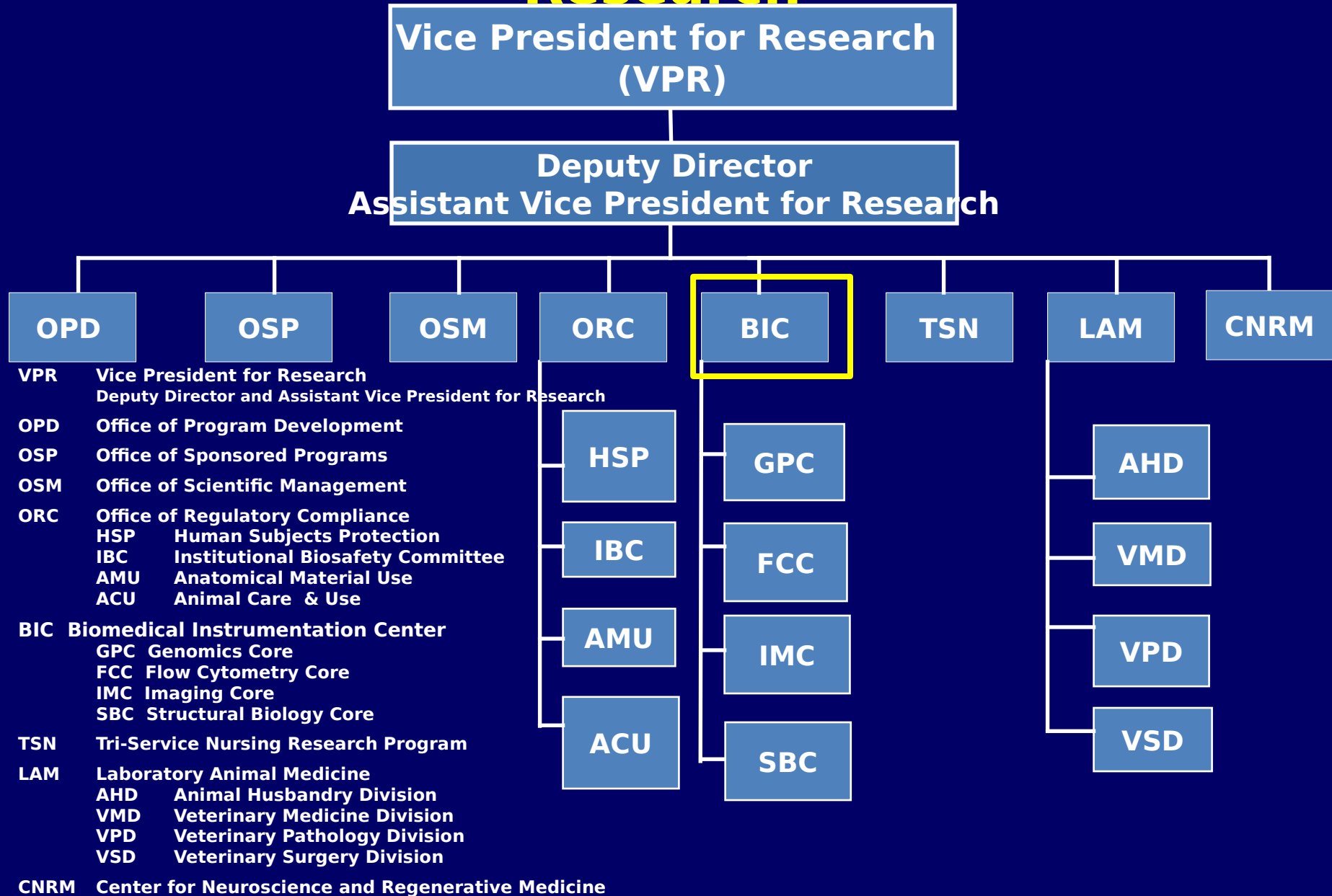
# LAM

- Resources Available
  - Conventional Multispecies housing
  - Barrier housing for rodents
  - Surgery suites for research and teaching
  - Surgery & Anesthesia technical assistance
  - Fluoroscopy
  - Necropsy
  - TBI & procedure rooms

# LAM

- Services Available:
  - Protocol & Animal model development
  - Protocol veterinary pre-IACUC review
  - Animal procurement
  - Animal quality assurance and quarantine
  - Animal housing and sanitation
  - Animal husbandry & health care

# Organizational Chart for Vice President for Research



# **Biomedical Instrumentation Center (BIC)**

LTC Felicia Langel, V.M.D.,  
Ph.D.

Director

[felicia.langel@usuhs.mil](mailto:felicia.langel@usuhs.mil)

301-295-9406

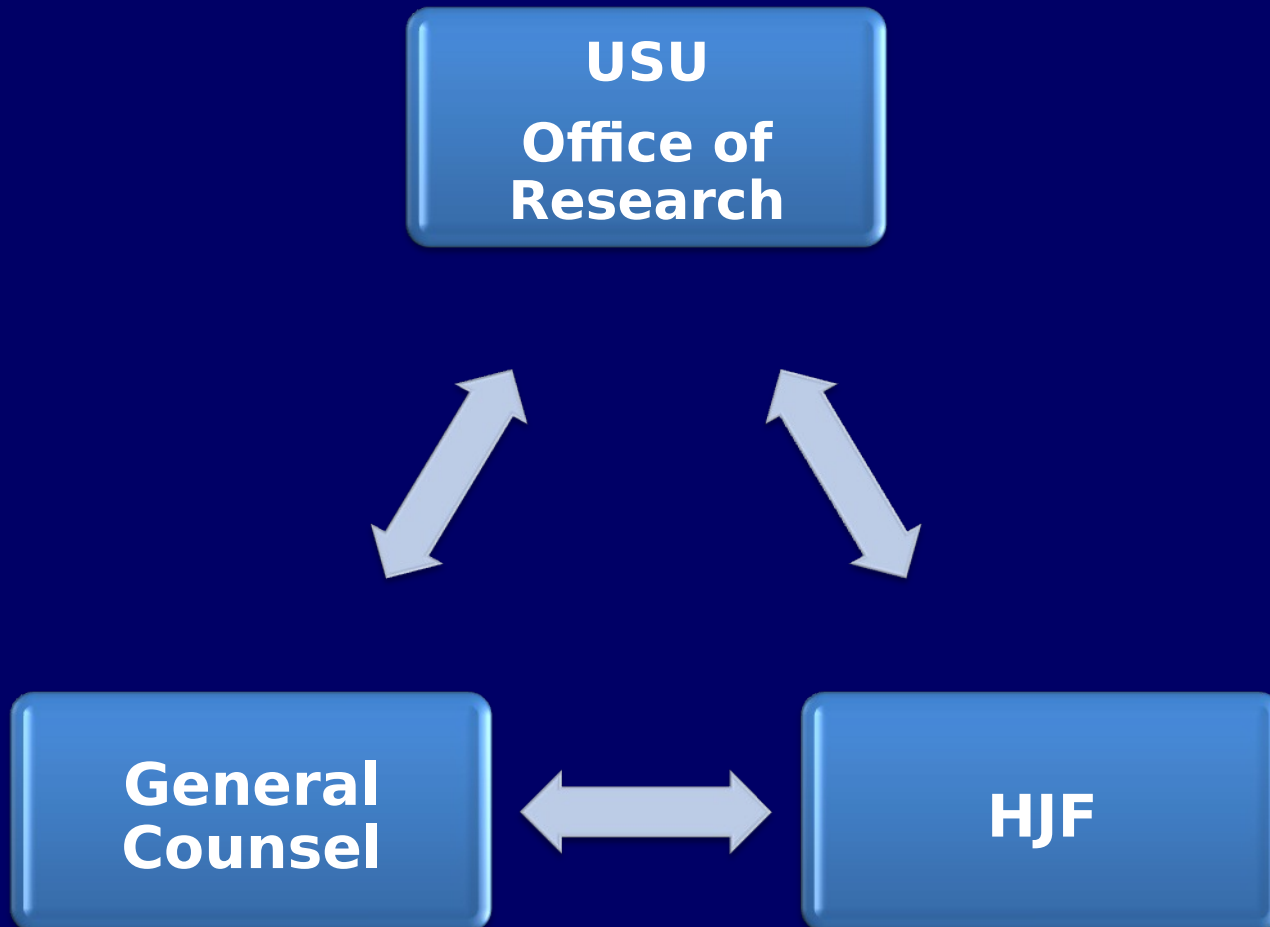
# **Biomedical Instrumentation Center (BIC)**

- BIC is the shared instrument facility for USU.
  - Open to all members of the USU community.
- Nominal fee-for-service
  - From full service to user-independent service, depending on the instrument and the user's level of training.
- Provide expertise in protocol design.
- Provide assistance with data collection and analysis.

# Biomedical Instrumentation Center (BIC)

- **Genomics**
  - DNA/RNA sequencing and synthesis
- **Microscopic Imaging**
  - Fixed and live microscopy
- **Flow Cytometry**
  - Fixed and live cell analysis and sorting
- **Histopathology**
  - Preparation of fixed and frozen tissues for microscopy
- **Structural Biology/Proteomics**
  - Molecular structure studies and protein/protein interactions
- **Translational Imaging**
  - *In vivo* and *ex vivo* MRI and PET/CT

# Joint Office of Technology Transfer (JOTT)



# **Joint Office of Technology Transfer (JOTT)**

Katie Swanson-Lipka, Ph.D.

Technology Transfer Director

techtransfer@hjf.org

301-295-0450 (USU Office)

240-694-2154 (HJF HQ)

[www.hjf.org/guide/services/other/techtransfer.ht  
ml](http://www.hjf.org/guide/services/other/techtransfer.html)

# **Joint Office of Technology Transfer (JOTT)**

Agatha Lee, Ph.D.

Technology Transfer Liaison

[alee@hjf.org](mailto:alee@hjf.org)

301-295-0450 (USU)

240-694-2277 (HJF)

# What Function does the Joint Office of Technology Transfer Serve?

To protect and commercialize novel technologies developed by USU and HIF researchers  
**Research → Inventions → Patents →**

## **Commercialization**

### **How?**

- Negotiating agreements affecting technology transfer
- Evaluating new invention disclosures
- Filing and prosecuting patent applications on novel inv
- Marketing and licensing novel technologies
  - Including biological materials

# Technology Transfer Services

- Material transfer agreements (MTA)
- Cooperative research and development agreements (CRADA)
- Nondisclosure agreements (NDA)
- Patent applications
- License agreements
- Royalty payments

**Any Questions?**



# Henry M. Jackson Foundation

- Created in 1983 as a non-profit corporation
- Chartered by Congress to “promote the welfare of the Uniformed Services University...”
  - Supports over 200 research projects at USU
  - Over 400 employees at USU, more than 80 with Visas
  - Administers more than 100 education funds and 70 endowments
- Located 6 miles north of USU on Rockville Pike

# HJF Support to USU

- Grant proposal submission assistance
- Post-award management
  - Human resources - recruiting, payroll, benefits, visas
  - Purchasing and vendor payments
  - Sub-award/sub-contract management
  - Financial management - 24/7 online reporting
  - Travel, graphics, communications services
- Education/endowment fund management
- Technology transfer

# HJF Sponsored Project Administrators

- Every department has a Sponsored Project Administrator (SPA)
- Salary supported by onsite indirect cost recovery
- SPAs support investigators with proposal development and submission and post-award administration
- SPAs act as liaison between investigator, USU and HJF administration

# What is a Patent?

- A Patent is a 20-year monopoly to prevent others from making, using or selling the patented invention without permission
- What is a patentable invention depends on many factors and is ultimately determined by the U.S. Patent and Trademark Office

# What are the Criteria for a Patent?

- **NOVEL** - The invention must be demonstrably different from prior art (Publicly available ideas, inventions, products)
- **USEFUL** - The invention must have some application or utility or be an improvement
- **WRITTEN DESCRIPTION** - Sufficient detail so that a person having ordinary skill in the art can make and use the invention
- **NON-OBVIOUS\*** - The invention cannot be obvious to a person of "Ordinary Skill" in the field when viewed in light of prior art

\* This is the most frequently cited reason by patent examiners as to why an invention is not patentable

# The Importance of Record Keeping

- Patents in the U.S. Are Granted to Those Who First Conceptualize an Invention and Reduce It to Practice
- Important to Document and Date
  - Conception of the Invention
  - Reduction of the Idea to Practice
- Use Bound Notebooks and Ink
  - Each Page Signed, Dated, and Witnessed

# Patenting and Public Disclosures

- Public Disclosures - Publications (Papers and Abstracts), Presentations, Posters, Seminars, Internet Postings, etc.
- **U.S.** - Can apply for a patent no later than 1 year after public disclosure
- **Foreign** - Rights are lost once a public disclosure is made unless a prior patent filing has been made

***Commercial value of inventions enhanced with worldwide patent protection***

# **Inventor Participation Increases the Probability of Success**

- **Inventor participates in drafting initial patent application by interacting with outside patent counsel**
- **Inventor participates throughout patent prosecution process**
  - Assists in addressing office actions from patent office
  - Adding additional data and new claims to the application
- **Inventor participation during commercialization**
  - Inventor assists in preparing non-confidential summaries of invention
  - Inventors are often the best source to identify licensees
  - Inventor participates in technical discussions with potential licensees
- **CRADAs with licensee or potential licensee**
  - Bring research money to the laboratory